REMARKS

Claims 51-59, 61-64, and 66-71 are pending. Claim 65 was canceled and claims 57 and 66 were amended; the amendments are fully supported by the specification as filed. No new matter has been added to this application.

35 U.S.C. § 112

Claims 51-54, and 61-71 were rejected for indefiniteness. The Examiner stated that "[c]laims 51-54, and 61-71 are vague and indefinite in the recitation of 'supplementary' with respect to the enzymes included in the composition, even when reading the claim in light of the specification. It is apparent that the term is used as providing a 'supplement', and appears redundant in this context." (See Office Action, page 2). In response, Applicant asserts that the term "supplementary enzyme" as recited in claim 51 refers to an enzyme that is an independent component of the administered composition, and as such, is not redundant in this context. The specification teaches that the addition of supplementary enzymes (*e.g.*, lactase, amylase, glucanase, and catalase) is optional in the formulation of the administered composition: "[d]ietary or supplementary enzymes such as lactase, amylase, glucanase, catalase and the like enzymes can also be included." (Emphasis added, see page 20, lines 10-11). Furthermore, the specification discloses Formulation 3, which includes Bacillus coagulans 2.5 $x10^8$ viable spores (approximately 17.5 mg) and lactase (200IU) . (See page 25, lines 27-37). Therefore, claim 51, as amended herein, is definite. Claims 52-54 and 61-69 depend from claim 51 and as such, are also definite. Similarly, the phrase "supplementary lactase" recited in claim 70 is definite for the reasons discussed above. Claim 71 depends from claim 70 and as such, is also definite.

The Examiner also indicated that claims 65-66 are vague and indefinite in the recitation of a suppository in the form of a "dried cell mass" or stabilized "gel", "paste" or "liquid suspension." Applicant has canceled claim 65 and has amended claim 66 to remove the term "liquid suspension" from the claim, such that claim 66, as amended herein, recites in part "said composition is in the form of a stabilized gel or paste." Applicant asserts that the terms "suppository" and "stabilized gel or paste" in the context of administration of a nutritional composition are well known to one skilled in the art. The specification at page 23, lines 26-29,

recites that "[a]dministration of a nutritional composition is, preferably, to the gastrointestinal tract by use of a gel, suspension, aerosol spray, capsule, tablet, wafer, powder or semi-solid formulation (*e.g.,* a suppository) containing a therapeutic composition of the present invention, all formulated using methods well-known within the art." Therefore, claim 66, as amended herein, is definite.

Accordingly, Applicant requests withdrawal of the rejections under § 112.

35 U.S.C. section 103

Claims 51-56, 58-59, 61-64 and 67-70 were rejected for obviousness over Hata in view of Paul and Hansen, in further view of Long and the ATCC Catalogue of Bacteria, the Examiner stating that "[a]ny mixture of the components embraced by the claims which does not exhibit an unexpected result is therefore *ipso facto* unpatentable." (See Office Action, page 4).

The pending claims are drawn to a unique combination of an isolated *Bacillus coagulans* bacterium, a fructo-oligosaccharide, a mineral gluconate, and a supplementary enzyme selected from the group consisting of lactase, amylase, glucanase and catalase. Applicants assert that this unique combination as required by the amended claims is non-obvious in view of the cited references, particularly considering the unexpected results observed in clinical trials using this composition. Applicant encloses herewith a Declaration from John Fisgus, M.D., stating that the effectiveness of treatments using a composition including *Bacillus coagulans* bacteria (400 million colony forming unites per dose) and a supplementary lactase (3000 units per dose) to treat lactose intolerance vastly exceeds both a) treatments using a lactase enzyme product (*e.g.,* Lactaid™) alone, and b) no treatment. Applicant also encloses herewith an Appendix disclosing the results of substantiating studies performed by Dr. Fisgus. These studies demonstrate that a composition including *Bacillus coagulans* bacteria and a supplementary lactase decreases the severity of common symptoms of lactose intolerance, including abdominal pain, cramping, diarrhea, bloating, gas and nausea at least twice as well as a lactase product alone; the *Bacillus coagulans* bacteria/supplementary lactase composition was about 25-fold better than lactase enzyme alone at reducing abdominal pain, and decreased nausea almost 82%, while lactase enzyme alone increased nausea by over 15%. (See Appendix A). Thus, the unique combination

of a *Bacillus coagulans* bacteria and a supplementary lactase demonstrate unexpected results over known treatments for medical conditions including lactose intolerance, and for this reason the pending claims are non-obvious in view of the cited references.

Claims 57 and 65-66 were rejected for obviousness over Hata in view of Reid, the Examiner stating that "Hata teach a process of providing a mammal with nutrients by orally administering yogurt composition containing *Bacillus coagulans*" and that "Reid adequately demonstrates that the administration to a mammal of a suppository comprising a lactic acid producing bacteria is old and well known in the art." (See Office Action, pages 3 and 5). Claim 65 has been canceled herein. Thus, the rejection is moot in regard to this claim. Regarding claims 57 and 66, Applicants note that claim 57 has been amended herein to require a suppository including an isolated *Bacillus coagulans* bacterium and a supplementary lactase. Reid does not teach or suggest a *Bacillus coagulans* bacterium, and neither Reid nor Hata teach or suggest a supplementary lactase, as required by amended claim 57. Therefore, claim 57 is non-obvious in view of the cited references. Claim 66 depends from claim 57 and, therefore, is also non-obvious in view of Reid and Hata.

Applicants request reconsideration and withdrawal of the rejections under §103.

recites that "[a]dministration of a nutritional composition is, preferably, to the gastrointestinal tract by use of a gel, suspension, aerosol spray, capsule, tablet, wafer, powder or semi-solid formulation (*e.g.*, a suppository) containing a therapeutic composition of the present invention, all formulated using methods well-known within the art." Therefore, claim 66, as amended herein, is definite.

Accordingly, Applicant requests withdrawal of the rejections under § 112.

35 U.S.C. section 103

Claims 51-56, 58-59, 61-64 and 67-70 were rejected for obviousness over Hata in view of Paul and Hansen, in further view of Long and the ATCC Catalogue of Bacteria, the Examiner stating that "[a]ny mixture of the components embraced by the claims which does not exhibit an unexpected result is therefore *ipso facto* unpatentable." (See Office Action, page 4).

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Applicants request reconsideration and withdrawal of the rejections under §103.

CONCLUSION

On the basis of the foregoing amendments, Applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact either of the undersigned at the telephone number provided below.

A request for continued Examination and required fee, a petition for a three-month extension of time and the petition fee pursuant to 37 C.F.R. § 1.17(a)(3) are filed herewith. With this extension, this response is due on or before May 5, 2003. The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 19374-504.

Respectfully submitted,

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Appendix: Marked up version of claim amendments

Claims 57 and 66 have been amended as follows:

57. (Amended) A method of increasing bioavailability of nutrients in a mammal comprising administering to said mammal a suppository, said suppository consisting essentially of an isolated *Bacillus coagulans* bacterium and a supplementary lactase.

65. (Canceled).

66. (Twice Amended) The method of claim 57, wherein said composition is in the form of a stabilized gel or paste[, or a stabilized liquid suspension].